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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,490	03/12/2001	Linda Burkly	CIBT-P01-114	2374

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FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT PAPER NUMBER

1646

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary

Application No.

09/804,490

Applicant(s)

BURKLY ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,7,8,11,12,26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,9,10 and 13-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 12/09/04, have been entered in full.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Claims 3, 4, 7, 8, 11, 12, 26 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/11/04. Applicant's arguments were addressed in the prior Office action, 9/7/04; the restriction requirement is maintained and made FINAL.

Maintained Rejections:

Claims 1, 2, 5, 6, 9, 10, 13-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patent No: 6,639,051, Wang-EA, in view of Ericson-J et al., Cell 87(661-673)1996 and U.S. Patent No: 4816567 as applied to claims 2, 6, 10, 21-23 and 25 previously and reiterated below.

Wang teaches methods comprising administering hedgehog agonists to promote epithelial cell growth, including hair growth, and also methods comprising administering hedgehog antagonists to inhibit epithelial cell growth, including hair growth, see lines 10-22 of col3, lines 39-55 of col 6, lines 24-28 of col 8, lines 17-28 of col 9, lines 5-14 of col 11, and topical administration see lines 65 col 11-bridging col 12.

Wang does not however specifically teach that the hedgehog antagonist be an anti-hedgehog antibody. However, the use of anti-hedgehog antibodies as hedgehog antagonists was widely appreciated at the time of the filing of the Wang parent application. For example, Ericson et al. use anti-hedgehog antibodies as hedgehog antagonists to block the generation of floor plate cells and motor neurons, see the second to the last paragraph of col 2 of page 661.

The claims also require that the anti-hedgehog antibodies be chimeric antibodies. Both Wang-EA, and Ericson-J et al. appear to be silent with respect to chimeric antibodies, however the optimization of in vivo use of antibodies by making them chimeric antibodies was well established at the time of filing the Wang parent application. U.S. Patent No: 4816567 teaches that in the art of antibody production, monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies are more preferred, see col 2, lines 40-65 and cols 15 D.6 and D.7).

Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made, with reasonable expectation of success use anti-hedgehog antibodies as antagonists when practicing the method of Wang, the motivation to do so is provided by both Wang, who teaches that any hedgehog therapeutic that inhibits the activity of wild type hedgehog should be used as a matter of ordinary optimization of operating parameters (col 7, lines 41-43), and by Ericson who teach that anti-hedgehog antibodies can inhibit the activity of wild type hedgehog (col 2 of page 661), and to further routinely optimize the operation parameters, to make a chimeric, or CDR grafted antibodies according to U.S. Patent No: 4816567 when practicing the invention of Wang as modified by Ericson. The motivation to do so is provided by U.S. Patent No: 4816567 wherein in is indicated that in the art of antibody production, monoclonal

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antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies are more preferred, see col 2, lines 40-65 and cols 15 D.6 and D.7).

Applicant argues that Ericson merely provide that anti-hedgehog antibodies antagonize hedgehog signaling in a particular in vitro neuronal explant system and provide no motivation to use them in any non-neuronal system such as hair. This argument has been fully considered but not deemed persuasive. It is Wang and not Ericson that provide the motivation to use hedgehog antagonist to inhibit epithelial/hair cells, see above.

Applicant argues that neither Wang or Ericson teach or suggest in that anti-hedgehog antibodies could have there effect on non-neuronal cells and tissues. This argument has been fully considered but not deemed persuasive. Wang teaches methods comprising administering hedgehog agonists to promote epithelial cell growth, including hair growth, and also methods comprising administering hedgehog antagonists to inhibit epithelial cell growth, including hair growth, see lines 10-22 of col3, lines 39-55 of col 6, lines 24-28 of col 8, lines 17-28 of col 9, lines 5-14 of col 11, and topical administration see lines 65 col 11-bridging col 12. Neither Wang nor Ericson suggest that certain antagonists would work on some hedgehog sensitive cells but not other, nor would one of ordinary skill in the art expect such a difference.

Applicant challenges the relevance of the 4816567 patent. This argument has been fully considered but not deemed persuasive. The 4816567 patent demonstrates that in the art of antibody use monoclonal antibodies are generally preferred to polyclonal antibodies (col 2, line 17), while CDR grafted and otherwise chimeric antibodies are more preferred, see col 2, lines 40-65 and cols 15 D.6 and D.7) as is old and well established in the art.

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Applicant argues that a non-obvious species is patentable over a patented genus. This is agreed to by the examiner, however, the examiner maintains that the instantly claimed species is obvious in view of Wang and what was commonly known in the art as evidenced by Ericson and the 4816567 patent.

Conclusion

This application contains claims 3, 4, 7, 8, 11, 12, 26 and 27 drawn to an invention nonelected with traverse in Applicant's response of 5/11/04. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX months.

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Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (571) 272-0829. Official papers filed by fax should be directed to 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

Elizabeth C. Kemmerer

W

ELIZABETH KEMMERER
PATENT EXAMINER

March 7, 2005